Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the Effects of Square Stepping Exercises and Rhythmic Aerobic Exercises on Balance in Elderly Women: a Randomized Controlled Trial

Protocol summary

Study aim

Compare effects on static balance Compare effects on dynamic balance Compare effects on functional balance Compare effects on walking ability Compare effects on quality of life

Design

Random, 3 parallel groups, single-blind, 45 elderly (15 each)

Settings and conduct

Rah-e Novin Health Center, Qazvin Randomization:Simple lottery (1:1:1), allocation concealment with sealed numbered envelopes. Blinding: Outcome assessor and statistician blinded; participants and providers not blinded.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age 60-80 years؛ Female gender؛ No regular physical activity in past 3 months؛ No contraindication for exercise؛ No neurological diseases, Parkinson's, or MS. Exclusion Criteria: Acute/chronic disease affecting balance (e.g., vertigo, vestibular disorders)؛ Fracture/surgery in lower extremity/spine in past 6 months؛ Use of medications affecting balance/CNS (e.g., benzodiazepines)؛ Inability to walk independently؛ Severe visual or hearing impairment؛ Concurrent participation in other training programs؛ BMI > 35.

Intervention groups

Group 1: 8 weeks square stepping (3 sessions/week, 60 min); Group 2: 8 weeks rhythmic aerobic (3 sessions/week, 60 min); Control: no intervention

Main outcome variables

Static balance (Sharpened Romberg – seconds) Dynamic balance (Y-Balance – % leg length) Functional balance (Berg Scale – score 0-56) Walking ability (TUG – seconds) Quality of life (SF-36 – score 0-135)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260623069934N1**
Registration date: **2026-08-10, 1405/05/19**
Registration timing: **prospective**

Last update: **2026-08-10, 1405/05/19**
Update count: **0**

Registration date

2026-08-10, 1405/05/19

Registrant information

Name

Mohaddeseh Shahsavari

Name of organization / entity

Shahid beheshti university

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-08-16, 1405/05/25

Expected recruitment end date

2026-10-22, 1405/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the Effects of Square Stepping Exercises and Rhythmic Aerobic Exercises on Balance in Elderly Women: a Randomized Controlled Trial

Public title
Comparison of Two Exercise Programs on Balance in Elderly Women

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Age 60-80 years Female gender No regular physical activity during the three months prior to the study No contraindication for physical activity No neurological diseases, Parkinson's disease, or Multiple Sclerosis (MS)

Exclusion criteria:
Presence of acute or chronic diseases affecting balance (e.g., chronic vertigo, vestibular disorders, orthostatic hypotension) History of fracture or surgery in the lower extremity or spine within the past 6 months Regular use of medications affecting balance or the central nervous system (e.g., benzodiazepines, antidepressants, muscle relaxants) Inability to walk independently without assistance (need for cane, walker, or helper) Severe visual or hearing impairment affecting exercise performance or instruction comprehension Concurrent participation in other regular training or rehabilitation programs Body Mass Index (BMI) greater than 35 kg/m²

Age
From **60 years** old to **80 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be performed using simple lottery method with a 1:1:1 allocation ratio. Each participant receives a unique code, then codes are written on small papers, placed in a container, and sequentially allocated to three groups (square stepping, rhythmic aerobic, and control). Sealed, numbered envelopes will be used for allocation concealment.

Blinding (investigator's opinion)
Single blinded

Blinding description
Due to the nature of the exercise-based interventions (square stepping and rhythmic aerobic exercises), complete blinding of participants and intervention providers is not feasible. However, to minimize detection bias, the outcome assessor and statistician will be blinded to group allocation. Participants: Not blinded (aware of their group due to the nature of the exercise protocols). Principal Investigator and Intervention Providers: Not blinded (supervise execution of specific exercise protocols). Outcome Assessor: Fully Blinded. All pre- and post-intervention assessments (Sharpened Romberg, Y-Balance, Berg Balance Scale, TUG, and SF-36) will be performed by an independent assessor with no knowledge of group allocation. Participants will be instructed not to reveal their training protocol to the assessor. Data Collectors/Support Staff: Blinded to group allocation. Data Analyst: Blinded. Data will be analyzed using coded groups (e.g., A, B, C) until the final statistical analysis is completed. Data Safety and Monitoring Committee: Not applicable (low-risk exercise interventions). Manuscript Writers: Not blinded (after completion of analysis and unblinding).

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
کمیته ی اخلاق در پژوهش دانشگاه شهید بهشتی تهران

Street address
Shahid Shahriari Square, Daneshjou Boulevard, Shahid Chamran Highway, Tehran, Iran

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1983969411

Approval date
2026-06-13, 1405/03/23

Ethics committee reference number
IR.SBU.REC.1405.070

Health conditions studied

1

Description of health condition studied
Balance Disorder in Elderly. Balance impairment in elderly women, associated with increased fall risk, reduced functional independence, and decreased quality of life.

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Static Balance
Timepoint
Pre-test (one week before intervention) and post-test (48 hours after the last training session)
Method of measurement
Sharpened Romberg Test using a stopwatch (time recorded in seconds)

2

Description
Dynamic Balance
Timepoint
Pre-test (one week before intervention) and post-test (48 hours after the last training session)
Method of measurement
Y-Balance Test using the standard Y-Balance Test kit and a tape measure (distance in centimeters, normalized to leg length)

3

Description
Functional Balance
Timepoint
Pre-test (one week before intervention) and post-test (48 hours after the last training session)
Method of measurement
Berg Balance Scale (14 items, each scored 0-4, maximum score 56)

4

Description
Walking Ability
Timepoint
Pre-test (one week before intervention) and post-test (48 hours after the last training session)
Method of measurement
Timed Up and Go Test using an armless chair, a stopwatch, and a measured 2.45-meter distance (time recorded in seconds)

5

Description
Quality of Life
Timepoint
Pre-test (one week before intervention) and post-test (48 hours after the last training session)
Method of measurement
SF-36 Quality of Life Questionnaire (36 items assessing four domains: physical health, mental health, social health, and general health; score range 0-135)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group 1: Square stepping exercises for 8 weeks, 3 sessions/week, 60 minutes/session (including 10 min warm-up, 40 min main exercise with 196 stepping patterns on a 250×100 cm mat, and 10 min cool-down). Exercises are performed in four directions (forward, backward, lateral, diagonal) with progressive difficulty from beginner to advanced levels.
Category
Prevention

2

Description
Intervention group: Intervention group 2: Rhythmic aerobic exercises for 8 weeks, 3 sessions/week, 60 minutes/session (including 10 min warm-up, 30 min basic aerobic movements such as step touch, cross step, lunge, high knee, butterfly, mambo, and 10 min cool-down). Exercise intensity is progressively increased.
Category
Prevention

3

Description
Control group: Control group: Receives no exercise intervention; participants continue their normal daily routine and are instructed not to initiate any new regular exercise program during the study period.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid beheshti university
Full name of responsible person
Mostafa Zarei
Street address
Shahid Shahriari Square, Daneshjou Boulevard, Shahid Beheshti University, Faculty of Sport Sciences and Health, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
shahid beheshti University
Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
shahid beheshti University
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University
Full name of responsible person
Mostafa Zarei
Position
Associate professor
Latest degree
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Other areas of specialty/work
Sport Medicine
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
De-identified individual participant data including demographic information (age, height, weight) and raw data for all primary outcome variables (Sharpened Romberg test scores, Y-Balance test scores, Berg Balance Scale scores, Timed Up and Go test scores, and SF-36 Quality of Life questionnaire scores) along with the data dictionary, study protocol, statistical analysis plan, and informed consent form will be fully shared.
When the data will become available and for how long
Access to data and documents will begin three months after publication of the main results and will continue for two years.
To whom data/document is available
Data and documents will be available to all researchers affiliated with academic, research, and scientific institutions (public and private), as well as clinical specialists (physiotherapists, geriatricians) who provide a methodologically sound proposal and demonstrate the capacity to analyze balance and aging-related data. Access for industry professionals is also possible upon submission of a valid research proposal and ethics committee approval.
Under which criteria data/document could be used
Permitted Purpose: Exclusively for scientific research and educational purposes in the fields of balance, aging, corrective exercises, and fall prevention. Conditions: Submission of a formal written request to the principal investigator including the title and objectives of the proposed analysis Provision of a methodologically sound analytical proposal (specifying variables, statistical tests, and software) Obtaining ethics committee approval from the requesting institution (if applicable) Signing a data confidentiality agreement and commitment to not re-identify participants Prohibition of commercial, legal use, or re-identification of participants Acknowledging the data source in all resulting publications and reports Providing a summary report of findings to the principal investigator upon completion of analysis
From where data/document is obtainable
Applicants may contact the Principal Investigator (Dr. Mostafa Zarei) through the following methods (in order of priority): First Priority (Email): mostafazarei@sbu.ac.ir Second Priority (Postal Mail): Shahid Beheshti University, Faculty of Sport Sciences and Health, Tehran, Iran, Postal Code: 1983969411 Third Priority (Phone): +98-21-29905838
What processes are involved for a request to access data/document
Step 1 (Days 1-3): Sending a formal email including the analytical proposal and identification documents to the principal investigator Step 2 (Days 4-7): Initial review by the principal investigator and request for possible revisions Step 3 (Days 8-10): Sending and signing the confidentiality agreement and commitment forms Step 4 (Days 11-14): Final review and approval by the principal investigator Step 5 (Days 15-21): Data de-identification and delivery via email or secure link Total Estimated Duration: Approximately 2 to 4 weeks (maximum 21 working days)
Comments
All data sharing procedures will be conducted in accordance with the International Committee of Medical Journal Editors (ICMJE) guidelines and with full respect for participant confidentiality and privacy. Data will only be shared with researchers who provide a methodologically sound proposal and commit to full compliance with ethical research standards. This trial has been registered in the Iranian Registry of Clinical Trials (IRCT) with the ID (to be inserted).